IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
No. 7:22-CV-73-M

CENTER FOR ENVIRONMENTAL HEALTH, ET AL., PLAINTIFFS v. MICHAEL S. REGAN, ADMINISTRATOR OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY, AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY, DEFENDANTS	**PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

INTRODUCTION

Plaintiffs in this case are six community and environmental justice groups in Eastern North Carolina – Cape Fear River Watch, Center for Environmental Health, Clean Cape Fear, Democracy Green, The NC Black Alliance and Toxic Free NC – who are concerned about the devastating impact on Cape Fear communities of four decades of pollution from Per- and Polyfluoroalkyl Substances ("PFAS"). This class of chemicals is persistent, ubiquitous in the environment and people's blood, and harmful to human health. PFAS are prompting urgent concern in the U.S. and internationally. In Eastern North Carolina, PFAS produced by The Chemours Company ("Chemours") in Fayetteville have contaminated groundwater and the Cape

Fear River adjacent to and downstream from the plant and are present in drinking water consumed by over 300,000 people.

In October 2020, plaintiffs petitioned the U.S. Environmental Protection Agency ("EPA") to require Chemours to conduct comprehensive health and environmental effects testing on 54 PFAS under section 4 of the Toxic Substances Control Act ("TSCA"). Defendants Exhibit 1. The 54 PFAS were selected because of the evidence of ongoing or probable exposure by residents from drinking water, waste discharges, air and other pathways. As the petition showed, there are little or no data on the hazards of the 54 PFAS so Cape Fear communities do not know how long-term exposure to these substances is affecting their health. To provide answers, plaintiffs' scientific advisors developed a testing program with several components. These included long-term studies in laboratory animals to determine whether certain PFAS detected in human blood and drinking water cause cancer, reproductive damage and other serious diseases, testing of the PFAS mixtures found in drinking water, and an epidemiological study of the Cape Fear population to examine the relationship between PFAS exposure and health disorders and disease.

In late 2021, EPA issued a decision purporting to "grant" the petition but refusing to issue test rules or orders under TSCA implementing the proposed testing program. Defendants Exhibit 2. In its decision, EPA declined to require testing on 47 of the 54 PFAS. While it pointed to previously planned studies on 7 other PFAS, these studies were not selected in response to the petition and would not provide data necessary to understand the effects of the PFAS on Cape Fear populations. Key studies requested by petitioners, including human epidemiological research on the Cape Fear population, long-term cancer studies of PFAS present in drinking water or blood and testing of PFAS mixtures found in drinking water, were also rejected. Faced

with a near-blanket rejection of their petition, plaintiffs reactivated their suit challenging EPA's petition response under section 21 of TSCA.

Now EPA seeks to dismiss plaintiffs' suit on the ground that its "grant" of the petition deprives the Court of subject matter jurisdiction. This motion should be denied.

Supreme Court and lower court decisions recognize that courts are not bound by the labels that agencies attach to their decisions but must determine their actual nature and effect. In their Amended Complaint, plaintiffs dispute that EPA granted their petition and demonstrate that it failed to grant nearly every one of their testing requests. Since the allegations in the Complaint must be accepted as true, this should be sufficient to defeat the motion to dismiss. Moreover, if accepted at face value, EPA's self-serving assertion that it "granted" the petition would negate the unusually broad and independent role that Congress assigned to district courts under section 21 and block them from making a *de novo* determination of the merits of TSCA citizens' petitions as the law requires. EPA's rewriting of section 21 is not only contrary to Congressional intent, but would deny the citizens of the lower Cape Fear River basin the right to ask the Court to hold EPA accountable.

In its petition response, EPA agreed that plaintiffs' petition justified the need for testing under section 4 of TSCA. But it then said that the key studies proposed by plaintiffs were unnecessary. And it further found that testing on almost all the 54 PFAS was unwarranted because of planned studies on a small number of "representative" PFAS under its National PFAS Testing Strategy. This categorical rejection of core elements of plaintiffs' testing proposal was not a minor difference of opinion on narrow technical issues but a "denial" of the petition in all but name. EPA may have its reasons for rejecting petitioners' testing proposals but their validity should be examined by the Court in a *de novo* proceeding under section 21(b)(4)(B), not walled

off from judicial scrutiny based on the fiction that the petition was "granted" and the Court has no jurisdiction.

Under TSCA section 21(b)(3), if EPA "grants" a petition to require testing, it "shall promptly commence an appropriate proceeding in accordance with [TSCA section 4]." EPA argues at length that its ongoing actions on PFAS under its October 18, 2021 PFAS Strategic Roadmap (Plaintiffs Exhibit 1) comprise such an "appropriate proceeding." However, this is irrelevant if the Court concludes that EPA in fact *denied* the petition. In this event, the need for testing would be determined by the Court in a *de novo* proceeding under section 21(b)(4)(B) and, if plaintiffs prevail, the Court must direct EPA to "initiate the action requested by the petitioner." Moreover, the actions EPA is taking do not constitute an "appropriate proceeding in accordance with [section 4]" because they do not initiate rulemakings or orders to require Chemours to test 47 of the 54 PFAS and thus are unresponsive to the petition that EPA purported to grant.

Finally, EPA is wrong that this case is moot. Defendants claim that "EPA granted Plaintiffs all available statutory relief under the TSCA Section 21 citizen petition process and the Court cannot provide Plaintiffs any further relief." Defendants Memorandum of Points and Authorities ("Def. Memo") at 20. However, there are numerous unresolved controversies, including whether EPA in fact "denied" plaintiffs' petition and whether plaintiffs can demonstrate in a *de novo* proceeding that the 54 PFAS meet the TSCA criteria for testing. Should plaintiffs prevail, it will be up to the Court, not EPA, to impose a remedy and it likely would far exceed the limited actions EPA is now taking.

STATEMENT OF THE CASE

Chemours' Pollution of the Cape Fear River Basin

This case is about the extensive PFAS contamination caused by the Chemours chemical manufacturing plant in Fayetteville and the absence of scientific data on the impacts of this contamination on the health of residents of the Cape Fear River basin.

The Chemours plant is located on a 2,150-acre site in a rural area south of Fayetteville, adjacent to the west bank of the Cape Fear River. Amended Complaint. ¶¶ 48-50, ECF 32; Plaintiffs' October 2020 Petition, Def. Exh. 1 at 10-11. The river continues for over 110 km to the City of Wilmington and then broadens into an estuary that ultimately flows into the Atlantic Ocean. The River is a source of drinking water for over 300,000 residents of Wilmington and other population centers downstream from or adjacent to the facility.

The facility was built and operated by DuPont and started producing PFAS in 1971. Id. In 2015, DuPont spun off its performance chemicals business to Chemours, a newly created company headquartered in Delaware, which then acquired the Fayetteville plant and several other former DuPont facilities. The plant is one of the largest US producers of PFAS. Its PFAS-based production operations involve hundreds if not thousands of individual PFAS, many of which have chemical structures that are as yet unidentified. Id.

Although it has been occurring for four decades, Chemours' extensive pollution of the Cape Fear River was not publicly known until recently. Starting in 2018, monitoring by Strynar et al. and Sun, et al., identified 10 PFAS in the River and drinking water downstream of the Fayetteville plant. In further sampling of the river downstream of the plant, McCord et al. found 37 unique PFAS molecules. Amen. Com. ¶ 52; Def. Exh. 1 at 11-12. Researchers at North Carolina State University also detected several of these compounds in the blood of residents of the lower Cape Fear region. Id. Sampling in the Cape Fear River downstream of the Chemours plant indicated that total PFAS concentrations (all substances combined) were 130,000 parts per

trillion (ppt). Water utilities serving Cape Fear communities subsequently identified numerous PFAS linked to Chemours in drinking water intakes. Id. As concern increased about surface water and drinking water contamination, monitoring of other environmental media for the presence of PFAS produced at the Fayetteville plant was initiated and demonstrated the presence of numerous PFAS in private wells, wastewater, stormwater, sediment, groundwater, soil, air emissions, and local produce. Amen. Com. ¶ 53. Recent sampling of drinking water systems and private wells documents the ongoing presence of several PFAS. Id, ¶ 54. Thus, human exposure to PFAS from drinking water and other sources continues.

The Dangers of PFAS

EPA has recognized that PFAS pose a serious threat to all Americans:[1]

> "Harmful per- and poly-fluoroalkyl substances (PFAS) are an urgent public health and environmental issue facing communities across the United States. PFAS have been manufactured and used in a variety of industries in the United States and around the globe since the 1940s, and they are still being used today. Because of the duration and breadth of use, PFAS can be found in surface water, groundwater, soil, and air—from remote rural areas to densely-populated urban centers. A growing body of scientific evidence shows that exposure at certain levels to specific PFAS can adversely impact human health and other living things. Despite these concerns, PFAS are still used in a wide range of consumer products and industrial applications."

PFAS are often called "forever" chemicals because they do not break down or degrade over time and therefore are highly persistent. Amen. Com. ¶ 42; Def. Exh. 1, at 9-10. Thus, they build up in the natural environment and in biological systems if they are bioaccumulative. These characteristics, combined with the high mobility of many PFAS, have resulted in their widespread distribution and pervasive presence both in environmental media and in people and wildlife around the globe. Id. PFAS have been detected in the blood of workers and the general

[1] EPA, *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024*, October 2021, at 5. The Roadmap is Plaintiffs' Exhibit 1.

population, with 99 percent of those sampled showing detectable levels of these compounds. Id.

The EPA TSCA office estimates that over 6500 PFAS are manufactured or used in the United States.[2] Testing on a small number of significant PFAS demonstrates concern for many serious health effects, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immunotoxicity, often at low doses. Amen. Com. ¶ 45; Def. Exh. 1, at 17-18. However. according to the Agency, "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects." Def. Exh. 1, at 21.

Relevant Provisions of TSCA

TSCA was enacted in 1976 to create a national program for assessing and managing the risks of chemicals to human health and the environment. Central to the law is imposing accountability on chemical manufacturers for conducting testing to determine the health and environmental effects of their chemicals. As stated in TSCA section 2(b), 15 U.S.C. §2601(b), "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and . . . the development of this information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."

This policy is implemented in section 4 of TSCA, 15 U.S.C. §2603. This provision, which Congress significantly strengthened in the 2016 TSCA amendments, provides EPA with broad authority to issue rules or orders directing manufacturers to undertake health and

[2] EPA. *National PFAS Testing Strategy: Identification of Candidate Per- and Polyfluoroalkyl Substances (PFAS) for Testing*. October 2021 ("National PFAS Testing Strategy") at 6. The Strategy is Plaintiffs' Exhibit 2.

environmental effects studies where EPA makes the necessary findings demonstrating the need for testing under section 4(a)(1). Such rules or orders must require that testing be conducted "to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience" and which are "relevant to a determination" whether the substance or mixture "does or does not present an unreasonable risk to health and the environment." Id., 15 U.S.C. § 2603(a)(1). Under section 4(b)(2)(A), test rules or orders may require a broad range of studies, including on "carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment." 15 U.S.C. (b)(2)(A). EPA may require "epidemiologic studies (research on human populations exposed to a chemical to ascertain whether a causal connection exists between that exposure and an increased incidence of death and disease) and studies on "mixtures" (combinations of substances that may have additive or synergistic effects where people are exposed to them concurrently). Id.; § 2603(a)(1)(B).

Section 21 of TSCA creates a petition process by which citizens can seek to compel EPA to exercise its authority to regulate chemicals under several provisions of the law. 15 U.S.C. § 2620. Described as an "unusually powerful procedure[] for citizens to force EPA's hand" in *Trumpeter Swan Society v EPA*, 774 F.3d 1037, 1939 (D.C. Cir. 2014), section 21(b)(3) requires EPA to respond to petitions within 90 days. If EPA denies the petition or fails to act within 90 days, the petitioner may file a civil action in federal district court to "compel the [EPA] Administrator to initiate a rulemaking proceeding as requested in the petition." 15 U.S.C. §2620(b)(4)(A).

Section 21(a) explicitly authorizes petitions for initiation of a rule or order under Section 4 requiring manufacturers to undertake testing. *Id.* § 2620(a). Under Section 21(b)(4)(B)(i),

where such petitions are denied, the district court must "order the Administrator to initiate the action requested by the petitioner" if it "demonstrates to the satisfaction of the court by a preponderance of the evidence" that the TSCA criteria for requiring testing have been met. In applying these criteria, the court must consider the evidence supporting the petition "in a *de novo* proceeding." 15 U.S.C. § 2620(b)(4)(B).

Plaintiffs' Testing Petition

The North Carolina residents represented by plaintiffs face serious health risks from long-term PFAS exposure but there are no or inadequate data on the health effects of the PFAS in their drinking water, the air they breathe, the food they eat and their blood. This lack of information on the health effects of these PFAS is depriving them and their medical professionals of important knowledge that would inform diagnosis, treatment and reduction of exposure. Amen. Com. ¶ 8.

On October 14, 2020, plaintiffs petitioned EPA under section 21 of TSCA to compel Chemours to undertake comprehensive health and environmental effects testing on 54 PFAS manufactured at its Fayetteville facility. Def. Exh.1. Petitioners selected these 54 PFAS based on evidence of known or anticipated human exposure as demonstrated by available data on their presence in human blood, drinking water, surface water, air emissions, rainwater, private wells, groundwater and locally grown produce. Id., at 12-14. The petition showed that the 54 PFAS meet the TSCA section 4(a)(1) criteria for testing because: (1) available data effects are insufficient to determine their effects on the health of Cape Fear basin residents and the basin's ecosystem, (2) they are similar to other tested PFAS known to cause adverse effects, and (3) they may present unreasonable risks because of the combination of potential toxicity and exposure. Id. at 16-22.

Based on the guidance of plaintiffs' scientific advisors, the petition proposed a

comprehensive testing program to develop sufficient data to determine the risks of the 54 PFAS to local communities. Id. at 23-30. Key elements of the program were experimental animal studies to determine whether the 54 PFAS have the adverse health effects linked to well-studied PFAS; an epidemiology study examining whether exposure to the 54 PFAS by the Cape Fear population is associated with increases in disease and mortality; testing on the mixtures of PFAS found in drinking water to determine whether they have additive or synergistic effects on health; and studies on the ecological effects of the 54 PFAS and their behavior in the environment.

EPA's Response to the Petition

The petition was denied by the Trump EPA on January 7, 2021. 86 Federal Register 6602. On March 3, 2021, plaintiffs filed suit against EPA under section 21 (ECF 1) and, on the next day, submitted a request for reconsideration to the Agency's new leadership.[3]

The Biden EPA granted reconsideration of the petition on September 16, 2021 and plaintiffs agreed to stay their suit during the reconsideration process. ECF 24-25. On December 28, 2021, EPA issued a new decision on the petition. Petition Response, Def. Exh. 2. The decision did not dispute plaintiffs' showings that the 54 PFAS met the criteria for testing in section 4(a)(1) of TSCA. Instead, EPA "determined that the petition sets forth facts demonstrating that it is appropriate to issue a section 4 order to address the health and environmental effects of PFAS" and said it "will exercise its TSCA authorities to compel development of information on PFAS." Id. at 8. However, EPA refused to issue test rules or orders for 47 of the 54 PFAS and concluded that nearly all of the studies that petitioners

[3] Amend. Com., ¶¶ 69-76. Because the petition denial had faulted plaintiffs for failing to demonstrate the absence of data on the 54 PFAS, the reconsideration request included a systematic and comprehensive literature search by plaintiffs' consultants that examined both publicly available information sources and data-bases compiled by EPA. The search showed that the 54 PFAS lack most or all of the studies proposed in plaintiffs' petition. For example, 41 of the PFAS did not have *any* reported data for health and environmental effects.

requested were unnecessary.

Because plaintiffs considered EPA's decision a *denial* of their petition, they reactivated their suit and filed an Amended Complaint updating their allegations and claims.

STANDARD OF REVIEW

Defendants' motion to dismiss is based on Rule 12(b)(1) of the Federal Rules of Civil Procedure and, as defendants acknowledge, is a "facial challenge" to the legal sufficiency of plaintiffs' Amended Complaint. Def. Mem. at 12, n. 4. As the Supreme Court has held, a trial court should dismiss a complaint under Rule 12(b)(1) only when the jurisdictional allegations are "clearly . . . immaterial, made solely for the purpose of obtaining jurisdiction or where such a claim is wholly unsubstantial and frivolous." *Bell v. Hood*, 327 U.S. 678, 682 (1946). Thus, dismissal is not warranted "unless it appears to a certainty that the plaintiff would be entitled to no relief under any state of facts which could be proved in support of his claim." *Johnson v. Mueller,* 415 F.2d 354, 355 (4th Cir. 1969). Where the claimed basis for dismissal is "that a complaint simply fails to allege facts upon which subject matter jurisdiction can be based," the "facts alleged in the complaint are taken as true, and the motion must be denied if the complaint alleges sufficient facts to invoke subject matter jurisdiction*." Kerns v. U.S.*, 585 F.3d 187, 192 (4th Cir. 2009). As the Fourth Circuit held in *Adams v. Bain,* 697 F.2d 1213, 1219 (4th Cir. 1982), "where the jurisdictional facts are intertwined with the facts central to the merits of the dispute," the "entire factual dispute is appropriately resolved only by a proceeding on the merits."

ARGUMENT

I. THE COURT SHOULD REJECT EPA'S CLAIM THAT IT 'GRANTED' THE PETITION BECAUSE ITS PETITION RESPONSE WAS IN REALITY A DENIAL

The premise of defendants' motion to dismiss is that EPA "granted" plaintiffs' petition and there is no case or controversy for this Court to decide. However, plaintiffs contest this characterization in their Amended Complaint and maintain that EPA "denied" the petition because it rejected nearly all their requests for testing. Amend. Com. ¶¶ 82-121. If these allegations are accepted as true, the Court would plainly have subject-matter jurisdiction under section 21(b)(4)(A), which states that, "[i]f the Administrator *denies* a petition. . . the petitioner may file a civil action in district court of the United States to compel" the Agency to grant the relief sought (emphasis added).

Defendants ask the Court to unconditionally accept EPA's characterization of its petition response without examining whether it was in reality a "denial." This flies in the face of extensive case law recognizing that courts are not bound by the labels that agencies attach to their decisions but must determine their actual nature and effect. It also would nullify the broad and independent role that Congress assigned to district courts under section 21 by preventing them from making the *de novo* determination of the merits of TSCA citizens' petitions that the law requires.

A. Courts Look Behind the Label that Agencies Attach to their Actions and Examine Their Underlying Reality and Consequences

Numerous decisions address whether agency actions are unreviewable because they comprise non-binding "guidance" or are "legislative rules" subject to judicial review because they impose binding obligations. Since they involve the jurisdiction of the court, these decisions examine the agency's action *de novo* and independently determine its nature and effect. As the Supreme Court recently held, "agencies have never been able to avoid notice and comment simply by mislabeling their substantive pronouncements. On the contrary, courts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*, when deciding

whether statutory notice-and-comment demands apply." *Azar v. Allina Health Services* (2019) 139 S.Ct. 1804, 1812 (2019) (emphasis in original.

Numerous lower court decisions apply this principle. *See, e.g*. *Sorenson Commc'ns, Inc*. *v. F.C.C*., 567 F.3d 1215, 1223 (10th Cir. 2009) ("[t]he agency's own label for its action is not dispositive" of the Court's jurisdiction); *Tesoro Alaska Petroleum Co*. v. FERC, 234 F.3d 1286, 1293 (D.C. Cir. 2000) ("agencies may not use shell games to elude review"); *Guardian Federal Savings Loan Ass'n v. FSLIC,* 589 F.2d 658, 666-67 (D.C. Cir. 1978) ("If it appears that a so-called policy statement is in purpose or likely effect one that narrowly limits administrative discretion, it will be taken for what it is"); *Iowa League of Cities v. EPA,* 711 F.3d 844, 862 (8th Cir. 2013), ("to place any great weight on [EPA's characterization of its action] could permit an agency to disguise its promulgations through superficial formality, regardless of the brute force of reality)"; *Appalachian Power Company v. EPA,* 208 F.3d 1015, 1024 (D.C. Cir. 2000) ("[i]t is well-established that the agency may not escape the notice and comment requirements by labeling a major substantive [action] a mere interpretation"); and *Chiang v. Kempthorne*, 503 F.Supp.2d 343, 350 (D.D.C. 2007) ("Moreover, 'the agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the 'force of law,' but the record indicates otherwise'") (citationS omitted).

B. Accepting EPA's Characterization of Its Petition Response Would Negate the Independent Role of the Court In Determining Plaintiffs' Entitlement to Relief under Section 21

The D.C. Circuit has described section 21 as an "unusually powerful procedure[] for citizens to force EPA's hand. " *Trumpeter Swan Society v EPA*, supra, 774 F.3d at 1939. The court has also explained that "[c]itizen participation is broadly permitted [under TSCA] 'to ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital

authority.'" *Env. Def. Fund v. Reilly*, 909 F.2d 1497, 1499 (D.C. Cir. 1990) (quoting legislative history). In *Food & Water Watch, Inc. v. U.S. Envtl. Prot. Agency,* 302 F. Supp. 3d 1058, 1066 (N.D. Cal. 2018), the district court emphasized that "the overarching purpose of the TSCA is to protect the public from chemicals that pose an unreasonable risk to health and the environment, and citizen petitions are considered a powerful tool in forcing the EPA's hand in that regard." As the court noted, TSCA's legislative history underscores that "[t]he responsiveness of government is a critical concern and the citizens' petition provision will help to protect against lax administration of the [TSCA]." S. Rep. 94–698, reproduced at 1976 U.S.C.C.A.N. 4491, 4503. The court emphasized that "the role of citizen oversight, including access to federal courts, weighs considerably" in interpreting section 21.

These policies account for the striking decision of Congress to direct the district court to consider the merits of a petition "in a *de novo* proceeding." 15 U.S.C. § 2620(b)(4)(B). Such a "de novo proceeding in district court modeled after traditional trial-like proceedings" is a marked contrast to the typical judicial role of "review[ing] the soundness of the EPA's findings" to determine whether they are "supported by substantial evidence." *Food & Water Watch, Inc.,* 302 F. Supp. 3d at 1066, 1069.

Section 21 explicitly instructs district courts how to address petitions requesting the issuance of a rule or order requiring testing under section 4. Under section 21(b)(4)(B), the district court must, in a *de novo* proceeding, determine whether the plaintiff has "demonstrate[d] to the satisfaction of the court by a preponderance of the evidence" that:

> "(i)(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the *chemical substance to be subject to such rule or order* and (II) in the absence of such information, the *substance* may present an unreasonable risk to health or the environment . . . " (emphasis added).

If the court has made these determinations, it "shall order the Administrator to initiate the action requested by the petitioner."

This scheme in effect puts the Court in the position of the Agency. The Court must apply criteria for determining the need for testing very similar to those prescribed in section 4(a) for testing decisions by EPA.[4] The Court's application of these criteria is to be based on its own assessment of the evidence presented by the parties, without deference to prior EPA findings. The focus of this analysis is whether the preponderance of the evidence demonstrates that the *specific chemicals* proposed for testing in plaintiffs' petition meet the threshold in section 21(b)(4)(B) for requiring testing. If the Court finds that these standards have been met, the Court *must* direct EPA to initiate the test orders and/or rules "requested by the petitioner" and these orders and/or rules must apply to the *specific chemicals* which the Court has determined meet the testing criteria.

Defendants' interpretation of TSCA would negate the purposes of section 21 by precluding citizen access to judicial remedies and eliminating the expansive role of the district court in determining whether the standards for requiring EPA action have been met. The Agency could avoid any judicial accountability simply by declaring that it had "granted" a citizens' petition, even though (as here) it has initiated a sham "proceeding" that purports to address the petition but in fact does not grant the relief sought. Under this extreme approach, the Court would have to accept the label EPA applies to its decision and could not examine whether the petition response in fact comprises a "denial. "

[4] The two findings the court must make under section 21(b)(4)(B)(i) are similar to the findings EPA must make under section 4(a)(1)(A)(i)(I)-(II). However, EPA must make a third finding under clause III -- "testing of such substance or mixture with respect to such effects is necessary to develop such information" – that the Court is not required to make under section 21(b)(4)(B).

This is not what Congress intended. As in the decisions described above, if EPA's response to the petition is "in purpose or likely effect" a denial, it should "be taken for what it is." EPA should not be allowed to defeat the Court's jurisdiction by the "use of shell games to elude review."

II. HOWEVER LABELED, EPA'S PETITION RESPONSE WAS A DENIAL BECAUSE IT REFUSED TO GRANT NEARLY ALL OF THE REQUESTS FOR TESTING IN THE PETITION

A point-by-point comparison of plaintiffs' October 14, 2020 petition and EPA's December 22, 2021 response leaves no doubt that EPA failed to require the testing proposed in the petition.[5]

A. The Petition Requested a Detailed and Extensive Testing Program on 54 PFAS and Showed that these PFAS Met the Section 4 Criteria for Testing

The 54 PFAS included in the petition were selected based on specific evidence of known or anticipated human exposure by residents of the Cape Fear River basin. For each PFAS, the petition identified available data on their presence in human sera, drinking water, surface water, air emissions, rainwater, private wells, groundwater and produce. Def. Exh. 1, at 12-14. The 54 PFAS were divided into Tier 1 substances (for which there is substantial known human exposure as evidenced by their detection in blood, food or drinking water) and Tier 2 substances (for which human exposure is probable based on detection in environmental media). Id. at 12.

The petition demonstrated that the 54 PFAS meet the criteria for testing in section 4(a)(1)(A) of TSCA. As it showed, these PFAS "may present an unreasonable risk" to health because they are analogous to other PFAS known to have adverse health effects and have actual

[5] Plaintiffs agree that EPA's December 28, 2021 decision is the operative statement of its petition response and supersedes the earlier petition denial of January 7, 2021, 86 Fed. Reg. 6602 (Jan. 22. 2201), which is now moot.

or potential exposure.[6] Id. at 16-20. The petition also showed that data on the health and environmental effects of the 54 PFAS are either non-existent or insufficient for determining whether they present unreasonable risks to people and the Cape Fear River ecosystem and that testing is necessary to develop such information. Id. at 20-23.

Plaintiffs' scientific consultants then developed a testing program that would determine whether the 54 PFAS do or do not have the adverse health effects linked to other well-studied PFAS. Id. at 23-30. The specific studies included in the program were selected because of their ability to provide data not now available that would define whether and how the 54 PFAS may harm residents of exposed communities and aquatic species in the River. Id. at 23-24. The proposed program had the following key elements (id. at 2-3):

Experimental Animal Studies

- Compounds in both Tiers would undergo 28-day repeated dose rodent toxicology studies coupled with reproductive and developmental toxicity screening assays, examining critical PFAS endpoints including hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity.

- These studies would also be conducted on three mixtures of PFAS representative of the groups of substances to which residents have been exposed through drinking water, human sera and other pathways.

- Multigeneration or extended one-generation and 2-year rodent carcinogenicity studies would be conducted on the 14 Tier 1 substances in recognition of the evidence of direct and substantial human exposure and the concerns for these endpoints demonstrated by other PFAS.

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[6] The bar for making these determinations is a low one. In *Chemical Manufacturers Association v. U.S. Environmental Protection Agency,* 859 F.2d 977, 984-987 (1988), the D.C. Circuit concluded that Congress did not expect that EPA would have to document to a certainty the existence of an 'unreasonable risk' before it could require testing" It added that "the word 'may' in section 4(a)(1)(A) was intended to focus the Agency's attention on chemical substances 'about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine the effects of the substance or mixture on health or the environment.'" Thus, EPA need not demonstrate that exposure or toxicity is "probable" but may "rely on inferences in issuing a section 4 test rule, so long as all the evidence . . . indicates a more-than-theoretical probability of exposure." Inferences can also support findings of potential toxicity since "Congress explicitly contemplated that EPA would base test rules on comparisons among structurally similar chemicals." 859 F.2d at 988-991.

- Most studies would be carried out in two species (mice and rats) and by oral routes of administration, except inhalation would be used for volatile chemicals.

- Toxicokinetic studies would be conducted to characterize relationships between serum concentrations and dermal, oral and inhalation exposures in the test species, and to evaluate biological half-life and potential for bioaccumulation.

Human Studies

- A human health study for the Cape Fear watershed would be conducted to determine the relationship between exposure to the mixtures of PFAS that characterize current and historical exposure in the Cape Fear watershed and health outcomes among exposed populations.

- Testing would also be performed to determine human half-lives of the listed chemicals through longitudinal biomonitoring and exposure estimation in workers.

Ecological Effects/Fate and Transport and Physical-Chemical Properties Studies

- Testing would include ecological effects studies, similar to studies conducted on other PFAS.

- EPA would require development of analytical standards where not currently available, physical- chemical properties tests, and fate and transport studies in order to identify and predict exposures.

B. The Petition Response Refuses to Require Testing on Nearly All 54 PFAS and Rejects Virtually All the Studies in Plaintiffs' Proposed Testing Program

EPA's December 28, 2021 petition response did not dispute that, as required by section 21(b)(4)(B), the 54 PFAS lacked sufficient information "to permit a reasoned evaluation of their health and environmental effects" and "in the absence of such information. . . may present an unreasonable risk to health or the environment. . ." EPA further acknowledged that "the vast majority of PFAS are 'data-poor', that is, lacking data that inform behavior in the environment or in exposed ecological or human populations." Def. Exh. 2, at 7.

Emphasizing that the Agency "understands, and shares, petitioners' concerns about the historic and ongoing exposures to PFAS in the Cape Fear River watershed of North Carolina,"

id., EPA then said that:

> "EPA has determined that the petition sets forth facts demonstrating that it is appropriate to issue a section 4 order to address the health and environmental effects of PFAS. As such, EPA is granting the petition and will exercise its TSCA authorities to compel development of information on PFAS."

Id. at 8. However, the remainder of the petition response backed away from this commitment to "exercise [EPA's] TSCA [testing] authorities." Thus, the Agency declined to require testing on 47 of the 54 PFAS. It also took the position that there was no need for the most important studies that the petition proposed, including human epidemiology assessments for the Cape Fear basin population, studies of the actual mixtures of PFAS present in drinking water and human blood, and long-term cancer studies on the Tier I PFAS with the highest human exposure.

In summary, the petition response:

- Failed to require testing on 47 of the 54 PFAS;
- Conditioned testing for 7 PFAS on a "tiered" approach that could result in no animal studies for the critical end-points highlighted in the petition;
- Did not address the petition's request for multigeneration or extended one-generation and 2-year rodent carcinogenicity studies on the 14 Tier 1 PFAS with substantial human exposure from drinking water and/or presence in human blood;
- Did not require any testing for GenX compounds – a set of PFAS receiving broad public attention in Eastern North Carolina -- despite the identification by EPA risk assessors of serious data gaps on this ubiquitous and harmful PFAS;
- Refused to require a comprehensive epidemiological study of North Carolina residents exposed to the PFAS pollution created by the Chemours facility;
- Rejected requiring biomonitoring of Chemours employees;
- Declined to require testing on PFAS mixtures found in the drinking water and/or blood of Cape Fear residents;
- Refused to require Chemours to develop and submit analytical standards and methods on the 54 PFAS; and
- Failed to address the petition's requests for ecotoxicity and fate and transport

studies on the 54 PFAS.

Amend. Com., at ¶ 83.

EPA now acknowledges that it "was not committing to every aspect of Plaintiffs' proposed testing program," but suggests that EPA was simply exercising its "discretion to determine the specific protocols and methodologies" it might require in a rule or order. Def. Mem. at 2, 16. This is misleading. EPA did *not* agree to the overall framework for testing presented in the petition and merely leave the technical details for later.[7] Repeatedly, it rejected requiring the *types of studies* the petition requested and choose not to compel testing on nearly *all the substances* that the petition proposed. This was a "denial" of the petition in all but name – not as EPA disingenuously claims, an effort to "conform[] its actions both in substance and timing to Plaintiffs' proposed testing protocols." Id. at 14.

EPA's petition response and now its motion point to its October 18, 2021 National PFAS Testing Strategy as demonstrating that EPA "granted" the petition. Def. Exh. 2, at 9-13; Def. Mem. at 7-9. However, this Strategy is not focused on the health impacts of PFAS on exposed communities. Rather, its purpose is to obtain data on substances "representative" of 70 large groupings of PFAS in order to understand variations in chemical structure that may impact the toxicity of the 6000+ known PFAS.[8] Thus, although the Strategy designates 7 of the 54 PFAS

[7] EPA suggests that it only disagreed with plaintiffs on the selection of "protocols and methodologies." Def. Mem. at 15. This reflects a misunderstanding of these terms. As used in TSCA and EPA regulations, they refer to the details of how testing is conducted, not the types of studies to be performed or the substances to be tested – the subjects on which plaintiffs' petition focused. The petition did not in fact address the " protocols" for the proposed studies except to incorporate by reference EPA "test guidelines," which are used to develop test-specific "protocols" after a rule or order has been issued. Def. Exh. 1, at 30-34.

[8] Thus, the Strategy states: "The Strategy develops categories of PFAS based on information about similarities in structure, physical-chemical properties, and existing test data on the toxicity of PFAS (both publicly available and submitted to EPA under TSCA). . . EPA will use the Strategy to identify important gaps in existing data and to select one or more candidate chemicals within identified categories for additional study. . . The information derived from testing will be used by the Agency to evaluate of toxicity and risks associated with this large class of chemicals, and could further inform the Agency's future research, monitoring, and regulatory efforts." Pl. Exh. 2 at 3-4.

for testing, this was unrelated to the petition and predated the petition response. Rather, EPA deemed the 7 substances representative of 7 of the 70 large PFAS subcategories identified in the Strategy.[9] Def. Exh. 1, at 9.

With respect to the other 47 PFAS in the petition, EPA argues that several do not require testing because they are "covered" by other "representative" PFAS that will undergo testing or "may be covered" by future testing on other subcategory representatives.[10] Def. Exh. 2, at 2-3. EPA's premise is that these substances do not need individual testing because their health and environmental effects can be adequately determined by testing a single chemical from the 24 large subcategories (containing 2,950 PFAS by EPA's estimate) to which these PFAS belong. Id., at 2-3.

However, both legally and scientifically, it is debatable whether EPA can "grant" a petition on 47 PFAS on the basis of testing on other substances that may have very different effects and not even be manufactured by Chemours or present in the Cape Fear basin. As described above, in *a de novo* proceeding under section 21, the Court must apply the TSCA testing criteria to the *specific substan*ces at issue in plaintiffs' petition and, if they meet these criteria, direct EPA to initiate action to test *these substances.* Moreover, plaintiffs and their scientific experts do not agree that EPA can reasonably reach conclusions about the health impacts of PFAS exposure on Cape Fear communities by "extrapolating" from data on a small number of other substances.[11] This is the exact type of contested issue on which the Court should

[9] For the small number of PFAS to be tested under the Strategy, EPA plans to require a "tiered" testing program that plaintiffs believe will likely not include the most important health effects studies proposed in the petition. Amend. Com. ¶¶ 88-89.

[10] EPA also claims that 15 of the 54 PFAS "do not fit the definition of PFAS used in developing the Testing Strategy." Def. Exh. 2, at 15-17. However, plaintiffs and their scientific advisors believe that these 15 substances are properly defined as PFAS and in any case independently meet the criteria for testing in sections 4 and 21 of TSCA.

[11] Thus, in a letter to defendant Regan of December 20, 2021, nearly 50 leading scientists said that:

hear expert testimony in a *de novo* proceeding,

Implying that the door is open to more testing on the 54 PFAS, EPA's petition response emphasizes that "EPA generally expects to take some immediate actions and to defer certain other actions pending development of additional information that will inform future decision-making." Def. Exh. 2, at 2. But these "deferred" actions are never specified and there is no indication they will include additional studies requested in the petition. For example, EPA's response to plaintiffs' request for an epidemiology study on Cape Fear residents is that:

> "Considering the multiple ongoing nationwide efforts to address community PFAS exposures and the significant resources it would take for EPA to initiate such a study, the Agency currently believes it is both appropriate and consistent with EPA's statutory obligations to continue to engage and partner with existing ongoing research efforts . . ."

Id., at 19. This can only be read as an unequivocal decision **not** to require a Cape Fear epidemiology study.[12]

Similarly, EPA rejects plaintiffs' proposal to require studies on three mixtures of PFAS representative of Cape Fear drinking water:

> "EPA believes that a better understanding of individual PFAS that have been strategically selected to be representative of thousands of PFAS – a goal that would be furthered by the category approach contemplated in EPA's Testing Strategy – will provide the tools to assess many more PFAS mixtures than an immediate focus on a limited few discrete

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> "[T]he testing strategy will have limited value in informing exposed communities about the health impacts of PFAS pollution because the 24 test substances were selected without regard to whether they are widespread in the environment and human blood and contribute significantly to exposure and risk. Thus, the strategy is unlikely to provide information on those PFAS with the greatest potential to harm exposed populations."

Amend. Com. ¶ 89.

[12] Both in its March 4, 2021 request for reconsideration and in a July 28, 2021 letter to Assistant Administrator Freedhoff, plaintiffs explained that the other federally-sponsored human studies on which EPA was relying are focused "on examining the health impacts of drinking water contamination associated with releases of firefighting foams (AFFF) from airports and military bases located in other parts of the country" and "will not provide data relevant to Cape Fear communities, which have distinct demographics and health conditions, have been chronically exposed to high concentrations of a mix of PFAS uniquely associated with the Chemours facility and its operations, and have experienced exposure by a specific set of drinking water and other pathways (e.g., inhalation and consumption of local produce, fish and game) unlikely to be found elsewhere." Amend. Com. ¶ 99. EPA did not address these points in its December 28, 2021 petition response.

PFAS mixtures . . . ."

Id. at 17. Again, the message is clear: EPA will **not** require the requested mixture studies.[13]

It is double-speak to describe these categorical rejections of key studies as "granting" plaintiffs' petition. EPA may have its reasons for rejecting these studies but their validity should be tested by the Court in a *de novo* proceeding under section 21(b)(4)(B), not walled off from judicial scrutiny based on the fiction that the petition was "granted" and the Court has no jurisdiction.

III. EPA'S CLAIM THAT IT INITIATED AN "APPROPRIATE PROCEEDING" IS IRRELEVANT TO THE COURT'S JURISDICTION AND CONTRARY TO TSCA

A. If EPA Denied Plaintiffs' Petition, the Court Has Jurisdiction and the "Proceeding" Commenced by EPA Has No Bearing on the Remedy the Court May Require

Under section 21(b)(3), if EPA "grants" a petition seeking to require testing, it "shall promptly commence an appropriate proceeding in accordance with [section 4]." EPA argues that the actions it is taking on PFAS comprise such an "appropriate proceeding." Def. Mem. at 15-19. However, if the Court determines that its petition response was in fact a *denial*, the adequacy of the "proceeding" commenced by the Agency is not relevant to the Court's jurisdiction. Nor does it dictate the remedy the Court must impose if plaintiffs prevail in a *de novo* proceeding before this Court. Section 21(b)(4)(B) is explicit that, if the preponderance of the evidence shows that the 54 PFAS meet the criteria for testing, "the court shall order the Administrator to initiate the action requested by the petitioner." Thus, EPA's concept of an "appropriate proceeding" would

[13] As the Amended Complaint explains, EPA's rationale is unsound because "the small fraction of substances out of the thousands of known PFAS to be tested under EPA's Strategy means that nearly all components of the mixtures found in drinking water and human blood in the Cape Fear basin will *not* undergo individual testing." Amend. Com. ¶ 109.

have no bearing on the steps that the Court would direct EPA to take if the evidence meets the section 21(b)(4)(B) criteria for requiring testing.

B. The Actions EPA Is Taking in Response to the Petition Do Not Comprise a "Proceeding" and Are Not "Appropriate" Under Section 4 of TSCA

In any case, EPA is simply incorrect that "the actions it intends to commence will directly address the concerns of the petitioners" and "address[] each of the petition's specific proposals." Def. Mem. at 8, 14. The only action EPA has taken to date is issuance of one testing order for a PFAS that is not within the scope of plaintiffs' petition. Id., at 8-9. It has not yet issued testing orders for the 23 other "representative" substances and has no timetable for doing so. Moreover, apart from the limited testing it plans to order under the National Testinhg Strategy on 7 of the 54 PFAS, EPA has not committed to any action that will "address the concerns of the petitioners." [14] In fact, as discussed above, EPA has effectively closed the door both to testing the remaining 47 PFAS and requiring the key studies requested in the petition.

At best, the actions that EPA characterizes as an "appropriate proceeding" comprise a vague and open-ended plan for possible future testing. These actions do not qualify as a "proceeding in accordance with [section 4]" of TSCA because they do not initiate a rulemaking or an order requiring testing, the two formal steps by which EPA carries out its testing authority under section 4(a)(1)(A). Nor are they an "appropriate" because they are not responsive to the petition EPA purports to be "granting."[15]

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[14] For example, the petition response states that EPA "is contributing to and reviewing numerous existing ongoing human studies" and evaluating "how to further advance and expand on these efforts" and "is conducting more in-depth analyses of the existing available data" on the 15 petition chemicals that it believes do not meet its definition of PFAS." Def. Exh. 2, at 3. EPA provides no specifics on what this work entails, when if ever it might be completed, and whether and how it could lead to additional testing.

[15] In context, the word "appropriate" connotes a proceeding that carries out the actions proposed in the petition, not one that takes unrelated actions that do not respond to the petition.

EPA argues that neither petitioners nor courts under section 21 can "dictate the results" of EPA's final testing requirements under the separation-of-powers doctrine. Motion, at 19. This is true but courts can and often do direct EPA to *propose* rules with specific provisions and set deadlines for initiating and completing rulemaking.[16] This is the precise course of action Congress envisioned when EPA grants a petition under section 21(b)(3) or a court requires it to initiate the "action requested by the petitioner" under section 21(b)(4)(B). But this is not what EPA has done here.

The proper remedy under section 21 is illustrated in a recent case involving a petition seeking a proposed rule under section 8(a) of TSCA to require industry to report on asbestos. *Asbestos Disease Awareness Org. v. Wheeler,* 508 F. Supp. 3d 707, 735 (N.D. Cal. 2020).[17] After rejecting the Agency's petition response, the court's order -- consistent with section 21(b)(4)(B) -- stated that "EPA is directed to initiate a rulemaking proceeding to require reporting on asbestos under . . . Section 8(a) of TSCA that addresses the information-gathering deficiencies identified herein." In contrast to its position here, EPA then entered into a settlement agreement[18] committing to propose a rule that included the reporting elements required by the court and setting a schedule for publishing the proposed rule and taking final action.[19] These

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[16] *See, e.g.*, *Cmty. Voice v. United States EPA,* 878 F.3d at 788 (EPA ordered to propose regulations amending its standards for preventing harmful exposure to lead-based paint); *Public Citizen Health Research Group v. Auchter*, 702 F.2d at 1157-59 (OSHA ordered to propose an emergency workplace standard for ethylene oxide); *Public Citizen Health Research Group v. Com'r, FDA*, 724 F. Supp. at 1023 (FDA ordered to issue regulation requiring standardized tampon absorbency labeling); *Environmental Defense Fund v. E.P.A.,* 852 F.2d 1316, 1331 (D.C. Cir. 1988) (EPA required to propose rule determining which processing wastes remain within a statutory exclusion).

[17] Because the petition had sought an "amendment" of an existing rule, the court applied the more deferential Administrative Procedure Act standard of review instead of conducting a *de novo* proceeding

[18] The settlement agreement, dated June 7, 2021, is attached to a stipulation and order entered in Case Nos. 3:19-CV-00871-EMC; 3:19-CV-03807-EMC (N.D. Cal.) (ECF 92).

[19] *Citizens for a Better Env't v. Thomas*, 704 F. Supp. 149, 152 (N.D. Ill. 1989), cited by EPA, in fact recognized that, [i]f a petitioner can satisfy the court by a preponderance of the evidence that the action requested in the petition conforms to the requirements of the Act, the court shall order [EPA] to initiate the rulemaking procedures requested by the petitioner." The court then rejected intervenors' constitutional challenge on the ground that section 21 did not confer authority on the court to dictate the elements of EPA's *final* rule and preempt its discretion. (The court did not mention testing orders, which were added to the law until 2016.) This reading of section 21 contradicts EPA's

actions – not the limited and tentative steps EPA describes in its petition response – commenced an "appropriate proceeding" under section 21.[20]

IV. PLAINTIFFS' CLAIMS ARE NOT MOOT

As EPA acknowledges**,** a suit is moot when "events have so transpired that the controversy has ended and there is no remedy for the court to impose." *Del Monte Fresh Produce Co. v. United State*s, 565 F. Supp. 2d 106, 110 (D.D.C. 2008). This is not the case here. There is a live controversy over whether EPA in fact "denied" plaintiffs' petition. If so, the Court must conduct a *de novo* proceeding to determine whether the 54 PFAS meet the section 21(b)(4)(B) criteria for requiring testing. Should the Court make this determination, the remedy will be to "order the Administrator to initiate the action requested by the petitioner." Such an order would necessarily call for the initiation of rulemaking and/or testing orders on the 54 PFAS to require the studies proposed in plaintiffs' petition. The "proceeding" EPA says it has commenced does not comes close to taking these actions.

CONCLUSION

Defendants' motion to dismiss this case for lack of subject matter jurisdiction should be denied.

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Respectfully submitted,

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claim that an "appropriate proceeding" can consist of a general plan or strategy that could but may not result in testing.

[20] That the Court would set deadlines for the initiation and completion of action by EPA is implicit in section 21(b)(4)(B), which states that "the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes" if resource limitations or higher priorities constrain EPA's ability to "initiate the action requested by the petitioner" on the schedule set by the court.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of July 2022, a true and correct copy of the foregoing Memorandum was filed electronically with the Clerk of the Court using CM/ECF. I also certify that the foregoing is being served on all counsel of record via Notice of Electronic Filing generated by CM/ECF.

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